

Aventis Pasteur



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 01N-0464

Vaccine Adverse Event Reporting System; Revised Form VAERS-2 [66 FR 58153, November 20, 2001]

21 January 2002

Dear Sir/Madam:

Aventis Pasteur Inc. would like to thank you for the opportunity to comment on the above-referenced proposed "Vaccine Adverse Event Reporting System; Revised Form VAERS-2." The form had been revised by deleting fields that FDA considers redundant or unnecessary, and by adding or revising data fields to ensure reporting clarity. We offer the following comments/suggestions for your consideration.

General Comments

Print is rather small. Moving or eliminating the margins could accommodate the additional room required by larger font sizes.

Boxes don't leave room for much information on prior history; may we suggest wording to the effect those text fields can be continued on the back of the form or on auxiliary separate pages.

Box A: Patient Information

Line 2. Parent/Guardian Name

Place line 2, Parent/Guardian Name, at bottom of Box A following Race/Ethnicity. Parent/Guardian Name field's current location suggests that Parent/Guardian Name may be submitted as the "Patient" erroneously.

Line 4. Patient's Occupation

This information is rarely received on spontaneous reports, especially those for children. It is of possible marginal value relating to the AE. As such, it is not worth the human, capital or programming resources to capture and report.

Date of Birth Box

Suggest renaming to "Date of Birth of Patient" (or Pt. Date of Birth) otherwise parent/guardians may enter their birth date in error.

01N-0464

C 4

Age at vaccination Box

Suggest renaming to "Patient Age at vaccination" (Pt. age at vaccination).

Date of Birth and Age at vaccination Boxes

Shouldn't these fields be numbered like the other fields?

Line 11. Race/Ethnicity

This information is rarely received on spontaneous reports. It is of possible marginal value relating to the spontaneous AE. As such, it is not worth the human, capital or programming resources to capture and report.

Box B: Vaccine Provider Information

Line 1. County where vaccine was administered:

Suggest placing "County" in bold type or otherwise emphasizing "County." Reporters may be tempted to enter their country.

Box 7. Vaccine was administered at:

Box 8. Vaccine was purchased by provider with:

This information is inconsistently supplied in spontaneous reports to manufacturers. It is of marginal value to the AE report. As such, it is not worth the human, capital or programming resources to capture and report. Suggest removing Box 7 and Box 8 in order to obtain some available space.

Box C: Reporter Information

Line 8. Reporter's relationship to patient

Add a checkbox for "Parent."

Box E: Adverse Event Information

Box 2. How soon after vaccination did these event(s) start?

The question about the units of time from vaccination to onset of events is redundant since the form is asking for date of vaccination and date of onset of adverse events (the period of time between the two dates can be calculated). Suggest to add "Time of AE onset" similar to "Time of vaccination" in Box D.

Box 3. Date of onset

Suggest changing to "Date of AE onset."

Box 4. Did this event cause the patient to visit the doctor?

Suggest changing to "Did this event cause the patient to visit the doctor *or E. R.?*"

Box 7. Check below if the patient:

Died check box

Suggest changing "Date" to "Death Date."

Was hospitalized after vaccination

The form asks if the subject "Was hospitalized after vaccination." This question can be confusing. May we suggest asking that the line be changed to "Subject was hospitalized because of the adverse event" (not if hospitalization occurred after vaccination).

We also suggest adding: "Date discharged: ____/____/____" and/or

"Number of days hospitalized: ____."

Was already hospitalized and his/her stay was prolonged by ____ days

It may be difficult to specify the number of days that a hospitalization was prolonged. We suggest to only asking if the event prolonged the hospitalization.

Had life-threatening event AND Experienced permanent disability

To avoid confusion regarding a date of a life-threatening event listed below:

"List event" to be changed to "List event: _____ * " and

"List disability" to be changed to "List disability: _____ *." (Add underscores to create a more definitive writing space.

Suggest adding text "*Continue on a separate page if necessary" at the bottom of the box containing Death, Life-threatening event, etc. (Box 7)

Box F: Patient's Prior Health History

Box 1, 2, 3 and instructions for box 4, we suggest changing "recipient" to "patient" or "vaccinee." To avoid any confusion, we suggest all references to the vaccinee in question be made to the "patient" or other designations of the vaccinee. This will make Box F consistent with Box A, "Patient Information," at the top of the form that alludes to the patient.

Box 3. List any medications the

Suggest changing to "List any non-vaccine medications the....."

Instructions Line for Box 4

Change Instructions Line for Box 4 from: "List any other vaccines administered to the recipient within 4 weeks of the date given in Box D above:" to "List any other vaccines administered to the patient within 4 weeks before or after the date given in Box D above."

Aventis Pasteur



Box G: For Secondary Reporters' Use Only

Box 2. Tracking Number"

Suggest changing to "2. Tracking Number (Mfr file number)."

Box 4. Type of secondary report

It has been promulgated that follow-up numbers for individual reports could be printed in this box rather than as part of the "Tracking Number". If so, then may we suggest that "Follow-up No. ____" similar to the appearance of follow-up numbers on a MedWatch form be added. An underscore following No. indicates where follow-up numbers should be mapped to by computer systems.

It appears that the designation CDC/FDA has been omitted from the Form VAERS-2. This was the only designation on the form that identified it as a CDC document as well as a FDA document. As such, the personal information on the form fell under the protection of public health patient privacy laws. It is suggested that this designation be returned to distinguish the duality of the form's purpose. In lower left hand corner of the entitled Form VAERS-1, suggest placing the "CDC/FDA" designation or "CDC/FDA VAERS-2 Form."

On behalf of Aventis Pasteur Inc., we appreciate the opportunity to comment on the proposed "Vaccine Adverse Event Reporting System; Revised Form VAERS-2" and thank you for your consideration.

Sincerely,

Maurice W. Harkum, Ph.D, RAC

for Ricky D. Smith
Acting Site Head,
Regulatory Affairs
and Authorized Official

RDS/MWH/kh



VACCINE ADVERSE EVENT REPORTING SYSTEM

P.O. Box 1100, Rockville, MD 20849-1100
24-Hour Toll Free Information Line 800-822-7967
This VAERS Form can be faxed toll-free to 877-721-0366
Web site: <http://www.vaers.org> e-mail: info@vaers.org

For VAERS Use ONLY

Box A: Patient Information			Box B: Vaccine Provider Information			Box C: Reporter Information		
1. Patient's Last Name, First Name, M.I.			1. County where vaccine was administered:			1. Reporter is the person listed: <input type="checkbox"/> In Box A <input type="checkbox"/> In Box B <input type="checkbox"/> Below		
2. Parent/Guardian Name (if patient is under 18 years)			2. Responsible Physician's Name:			2. Reporter's Name		
3. Patient's Telephone Number			3. Responsible Physician's Telephone Number:			3. Reporter's Telephone Number:		
4. Patient's Occupation (if patient is age 18 or over)			4. Responsible Physician's Facility Name:			4. Reporter's Facility/Organization Name		
5. Patient's Current Address			5. Responsible Physician's Facility Street Address:			5. Reporter's Street Address		
6. City	State	Zip	6. City	State	Zip	6. City	State	Zip
7. Date of Birth ____/____/____		8. Age at vaccination ____	7. Vaccine was administered at: <input type="checkbox"/> Physician's Office <input type="checkbox"/> Military Facility <input type="checkbox"/> Public Health Facility <input type="checkbox"/> Workplace <input type="checkbox"/> Hospital/Med. Center <input type="checkbox"/> School/Daycare <input type="checkbox"/> Other _____			7. Date form completed: ____/____/____		
9. Weight at birth (if under age 5) lbs. ____ oz. ____		10. Sex <input type="checkbox"/> M <input type="checkbox"/> F	8. Vaccine was purchased by provider with: <input type="checkbox"/> Private Funds <input type="checkbox"/> Other (please describe): <input type="checkbox"/> Public Funds <input type="checkbox"/> Military Funds			8. Reporter's relationship to patient <input type="checkbox"/> Family member <input type="checkbox"/> Military Corpsman <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Physicians' Assistant <input type="checkbox"/> Other Reporter (please describe below):		
11. Race/Ethnicity (check all that apply) <input type="checkbox"/> White <input type="checkbox"/> American Indian, Eskimo, or Aleut <input type="checkbox"/> Black <input type="checkbox"/> Asian or Pacific Islander <input type="checkbox"/> Hispanic <input type="checkbox"/> Other (may be of any race)								

Box D: Vaccination Information						
Provide information for all vaccines given on this date:	1. Vaccine Name	2. Manufacturer	3. Lot Number	Vaccination		4. Dose # in Series
				5. Route	6. Site	
1. Date of vaccination ____/____/____	a. _____	_____	_____	_____	_____	_____
2. Time of vaccination ____ AM <input type="checkbox"/> PM <input type="checkbox"/>	b. _____	_____	_____	_____	_____	_____
	c. _____	_____	_____	_____	_____	_____
	d. _____	_____	_____	_____	_____	_____
	e. _____	_____	_____	_____	_____	_____

Box E: Adverse Event Information		
1. Describe the signs and symptoms that occurred after this vaccination and treatment, if any. (Attach additional sheets if necessary)		2. Check below if the patient: <input type="checkbox"/> Died Date: ____/____/____ <input type="checkbox"/> Had life-threatening event List event: _____ <input type="checkbox"/> Was hospitalized after vaccination Date admitted: ____/____/____ <input type="checkbox"/> Was already hospitalized and his/her stay was prolonged by ____ days <input type="checkbox"/> Experienced permanent disability List disability: _____ <input type="checkbox"/> Required medical intervention to prevent any of the above outcomes. <input type="checkbox"/> Experienced none of the above
3. How soon after vaccination did these event(s) start? (check units) ____ Hours <input type="checkbox"/> Weeks <input type="checkbox"/> ____ Days <input type="checkbox"/> Months <input type="checkbox"/>	4. Did this event cause the patient to visit the doctor? <input type="checkbox"/> No If Yes, date of visit: ____/____/____ <input type="checkbox"/> Yes	5. Has the patient recovered to his/her original state of health? <input type="checkbox"/> Yes <input type="checkbox"/> Not Yet <input type="checkbox"/> No <input type="checkbox"/> Unknown
6. Date of onset: ____/____/____		7. List results of relevant diagnostic procedures or lab testing:

Box F: Patient's Prior Health History		
1. List recipient's pre-existing physician-diagnosed illnesses, allergies, and/or medical conditions.	2. List any acute illnesses the recipient was experiencing at the time of the vaccination(s) given in Box D.	3. List any medications the recipient was receiving at the time of the vaccination(s) given in Box D.

List any other vaccines administered to the recipient within 4 weeks of the date given in Box D above:						
4. Date vaccine given	5. Vaccine Name	6. Manufacturer	7. Lot Number	Vaccination		10. Dose # in Series
				8. Route	9. Site	
a. _____	_____	_____	_____	_____	_____	_____
b. _____	_____	_____	_____	_____	_____	_____

Box G: For Secondary Reporters' Use Only		
1. Secondary reporter type <input type="checkbox"/> Vaccine Manufacturer FDA Lic. # _____ <input type="checkbox"/> State Immunization Coord. State _____ <input type="checkbox"/> Immunization Registry Name: _____	2. Tracking Number _____	3. Date received ____/____/____
		4. Type of secondary report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up <input type="checkbox"/> Mfrs. 15-day
		5. Does this report qualify as OMIC? <input type="checkbox"/> Yes <input type="checkbox"/> No

Form VAERS-2
(revised Jul 2001)

Healthcare providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Reportable Events Table following immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of the immunization grant awards.

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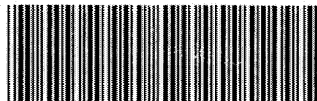
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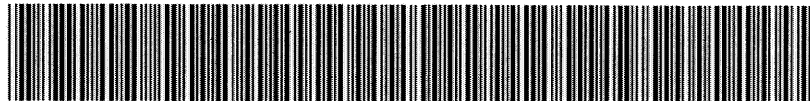


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